

FORM PTO-1449 (Rev. 2-32)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 36193	SERIAL NO. 10/536,584
INFORMATION DISCLOSURE STATEMENT BY APPLICANT  (Use several sheets if necessary)		APPLICANT: Jallal Messadek	
		FILING DATE: April 7, 2006	GROUP:1615 CONF. NO: 9204

**U.S. PATENT DOCUMENTS**

EXAM. INITIAL	DOCUMENT NUMBER	INVENTOR NAME	CLASS	SUB- CLASS	ISSUE DATE (PATENT); PUBLICATION DATE (PUBLISHED APPLICATION); OR FILING DATE (NON-PUBLISHED APPLICATION)
	2006/0233877	Messadek et al.			October 19, 2006
	5 7 1 6 9 4 1	Rabinoff			February 10, 1998
	2002/0183380	Hunter			December 5, 2002

**FOREIGN PATENT DOCUMENTS**

	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
						YES	NO
	FR 2,590M (927 734)	12 Mars 1963	France			X (see other docs)	
	WO 02/062322	15 August 2002	WIPO			X	
	WO 02/00213	3 January 2002	WIPO			X	
	WO 2004/032916	22 April 2004	WIPO			X	
	WO 97/38686	23 October 1997	WIPO			X	
	FR 70.47549 (2.119.889)	31 Decembre 1970	France			X (google only)	

**OTHER DOCUMENTS (Including Publisher, Author, Title,  
Relevant Pages, and Date and Place of Publication)**

		McGregor et al, "A Controlled Trial of the Effect of Folate Supplements on Homocysteine, Lipids and Hemorheology in End-State Renal Disease," Nephron, Vol. 85, No. 3, 2000, 215-220
		Gurfinkel et al., "Fast platelet suppression by lysine acetylsalicylate in chronic stable coronary patients. Potential clinical impact over regular aspirin for coronary syndromes," Clin. Cardiol., 2000 Sep;23(9):697-700.
		Klasing et al., "Dietary Betaine Increases Intraepithelial Lymphocytes in the Duodenum of Coccidia-Infected Chicks and Increases Functional Properties of Phagocytes," 2002, The American Society for Nutritional Sciences, J. Nutr, 132:2274-2282, 2002
		Schmidt et al., "Total nitric oxide production is low in patients with chronic renal disease," Kidney International, 2000, 58, 1261-1266
		Letter Regarding Dietary Supplement Health Claim for Folic Acid, Vitamin B6, and Vitamin B12 and Vascular Disease (Docket No. 99P-3029), to Jonathan W. Emord of Emord & Associates, PC, from Christine J. Lewis of the FDA, November 28, 2000
		Malinow, "Plasma homocyst(e)ine and arterial occlusive diseases: a mini-review," Clin. Chem, 1995 Jan;41(1):173-6
		al Awami et al., "Homocysteine levels in patients with Raynaud's phenomenon," Vasa. 2002 May; 31(2): 87-90
		Stammler et al., "The prevalence of hyperhomocysteinemia in thromboangiitis obliterans. Does homocysteine play a role pathogenetically?" Dtsch Med Wochenschr, 1996 Nove 15;121(46):1417-23.
		English Translation of French Patent 2,590M issued on June 15, 1964, 11 pages

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		4 9 6 8 7 1 9	Brevetti			November 6, 1990
		2002/0065320	Messadek			May 30, 2002
		6 0 0 8 2 2 1	Smith et al.			December 28, 1999
		6 6 2 4 1 8 0	South et al.			September 23, 2003
		6 7 6 2 0 2 5	Cubicciotti			July 13, 2004

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
		WO 2004/049095	10 June 2004	WIPO			X	
		WO 01/56609	9 August 2001	WIPO			X (ab- stract only)	
		WO 02/47493	20 June 2002	WIPO			X	
		WO 2005/065675	July 21, 2005	WIPO			X	
		WO 2005/004854	20 January 2005	WIPO			X (ab- stract only)	

**OTHER DOCUMENTS (Including Publisher, Author, Title,  
Relevant Pages, and Date and Place of Publication)**

		McCarty, "Co-administration of equimolar doses of betaine may alleviate the hepatotoxic risk associated with niacin therapy," Med-Hypothesis, 2000 Sep; 55(3): 189-94
		Letter regarding Petition for Health Claim: Folic Acid, Vitamin B6, and Vitamin B12 Dietary Supplements and Vascular Disease [Docket No. 99P-3029], to Jonathan W. Emord of Emord & Associatees from Christine J. Lewis of the FDA, February 9, 2001
		Birnie et al., "Antimicrobial Evaluation of N-Alkyl Betaines and N-Alkly-N,N-Dimethylamine Oxides with Variations in Chain Length," Antimicrobial Agents and Chemotherapy, Sept., 2000, p. 2514-2517
		Palatka Karoly et al., "Changes in the expression and distribution of the inducible and endothelial nitric oxide synthase in mucosal biopsy specimens of inflammatory bowel disease," Scandinavian Journal of Gastroenterology, 2005, vol. 40, no. 6, pp. 670-680
		van Hoek, "Non-alcoholic fatty liver disease: a brief review," Scandinavian Journal of Gastroenterology Supplement, 2004;(241):56-9.
		Mendes et al., "Recent advances in the treatment of non-alcoholic fatty liver disease," Expert Opin. Investig. Drugs, 2005 Jan;14(1):29-35.

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	US 2006/0233877	Messadek et al.			October 19, 2006
	US 2006/0034918	Messadek			February 16, 2006
	US 2006/0128657	Messadek			June 15, 2006

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						YES      NO
	WO 2005/011645	10 February 2005	WIPO			X
	WO 2004/049095	10 June 2004	WIPO			X
	WO 2005/011642	10 February 2005	WIPO			X
	WO 2006/007671	26 January 2006	WIPO			X (google trans- lation)

**OTHER DOCUMENTS (Including Publisher, Author, Title,  
Relevant Pages, and Date and Place of Publication)**

		Korzh, "Relationship Between Endothelial Nitric Oxide Synthesis and Low-Grade Chronic Inflammation," European Atherosclerosis Society, 73rd EAS Congress, Salzburg, Austria, July 7-10, 2002
		Didier et al., "Distal cutaneous necrosis, an unusual etiology: hyperhomocysteinemia," <u>Ann Dermatol Venereol</u> , 1999 Nov;126(11):822-5; PMID: 10612875
		Gurfinkel et al., "Fast Platelet Suppression by Lycine Acetylsalicylate in Chronic Stable Coronary Patients. Potential Clinical Impact Over Regular Aspirin for Coronary Syndromes," Abstracts--Myocardial Ischemia and Infarction, JACC, February 2000, 408A-409A
		Bonaa et al., "Homocysteine lowering and cardiovascular events after acute myocardial infarction,: <u>N. Eng. J. Med.</u> , 2006 April 13.; 354(15):1578-88. Epub 2006 March 12.
		Lonn et al., "Homocysteine lowering folic acid and B vitamins in vascular disease," <u>N. Eng. J. Med.</u> , 2006 April 13;354(15):1567-77. Epub 2006 March 12.
		Approval of Cilostazol, January 06, 2006, Center for Drug Evaluation and Research, <a href="http://www.fda.gov/cder/news/cilostazol/approval.htm">www.fda.gov/cder/news/cilostazol/approval.htm</a>

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		US 2003/0203878	Flashner-Barak et al.			October 30, 2003
		6 8 8 1 4 2 0	Flashner-Barak et al.			April 19, 2005

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		WO 02/066002	August 29, 2002	WIPO			X	
		WO 98/56497	December 17, 1998	WIPO			X	
		WO 99/45913	September 16, 1999	WIPO			X	
		WO 04/091601	October 28, 2004	WIPO			X	

**OTHER DOCUMENTS (Including Publisher, Author, Title,  
Relevant Pages, and Date and Place of Publication)**

		Carman and Fernandez, "A Primary Care Approach to the Patient with Claudication," American Family Physician, Vol 61, No. 4, February 15, 2000, <a href="http://www.aafp.org/afp/20000215/1027.html">http://www.aafp.org/afp/20000215/1027.html</a> , 8 pages
		Beaufour and Beaufour, "Nouvelles associations antinévralgiques à tolérance améliorée," Brevet Spécial De Médicament, P.V. no. 927.734, No. 2.590, 1964, pp. 1-5
		2/23/96 Chinese document (pp. 91-93) with English translation titled "Homocysteine and Vascular Disease," 5 pages
		Da Silva and Sobel, Abstract from Entrez-PubMed web page entitled "Anticoagulants: to bleed or not to bleed, that is the question," Semin Vasc. Surg. 2002 Dec;15(4):256-67, 1 page
		JACC Abstracts, Myocardial Ischemia and Infarction, February 2000, 1196-107, pp. 408-409
		Lasch H.G., Abstract from Entrez-PubMed web page entitled "Principles of Drug Prevention of Thrombosis," Langenbecks Arch Chir., 1986;369:451-7, 1 page
		Marcel et al., Abstract from Entrez-PubMed web page entitled "From Virchow to red cells (the unended quest).", Ric Clin Lab., 1983;13 Suppl 3:71-81, 1 page
		I. Zöllei et al., Betaine-Palmitate Reduces Acetylsalicylic Acid-induced Gastric Damage in Rats, Scand J. Gastroenterol 2001 (8), pp. 811-816
		Antithrombotic effect of Betaine, Bio Ethic, January 2003, pp. 1-30
		Copy of Office Action in 09/945,391 dated November 5, 2002, 5 pages
		Copy of Office Action in 09/945,391 dated June 4, 2003, 14 pages
		Copy of Office Action in 10/635,048 dated December 6, 2005, 8 pages
		Copy of Office Action in 10/635,048 dated December 21, 2006, 16 pages
		Copy of Office Action in 10/635,048 dated September 20, 2007, 25 pages

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